

COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, VA 22313-1450



Docket No.: 478.1074  
Date: June 16, 2006

In re application of: David MORTON, et al.  
Serial No.: 10/570,902 ✓  
Filed: March 7, 2006  
For: **METHODS FOR PREPARING PHARMACEUTICAL COMPOSITIONS**

Sir:

Transmitted herewith is a **Supplemental Information Disclosure Statement** in the above-identified application.

- ☐ Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.
- ☐ Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.
- ☒ No fee for additional claims is required.
- ☐ A filing fee for additional claims calculated as shown below, is required:

- ☒ Also transmitted herewith are:
  - ☐ Petition for month extension under 37 C.F.R. 1.136
  - ☒ Other: **Form PTO 1449 and Appendix A**

- ☐ Check(s) in the amount of **\$0.00** is/are attached to cover:
  - ☐ Filing fee for additional claims under 37 C.F.R. 1.16
  - ☐ Petition for month extension under 37 C.F.R. 1.136
  - ☐ Other:

- ☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.

- ☒ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
- ☒ Any patent application processing fees under 37 C.F.R. 1.17.
- ☒ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

  
Cary S. Kappel, Reg. No. 36,561  
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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with sufficient postage to the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on June 16, 2006.  
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: 

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Re: Application of: David MORTON *et al.*  
Serial No.: 10/570,902  
Filed: March 7, 2006  
For: **METHODS FOR PREPARING PHARMACEUTICAL  
COMPOSITIONS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

June 16, 2006

**SUPPLEMENTAL INFORMATION DISCLOSURE**  
**STATEMENT UNDER 37 C.F.R. § 1.56**

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (1 sheet) for consideration by the Examiner in connection with the examination of the above-identified patent application.

Applicants also respectfully advise the Examiner of the following co-pending U.S. patent applications and granted patent, all of which are commonly assigned to the owners of the instant application:

U.S. Patent Application Serial No. 09/000,065, "Powders Comprising Anti-adherent Materials for Use in Dry Powder Inhalers," filed June 16, 1998; issued as U.S. Patent No. 6,475,523 on November 5, 2002, listed as reference AA on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 11/054,074, "Powders Comprising Anti-adherent Materials for Use in Dry Powder Inhalers," filed February 9, 2005; published as U.S. Publication No. 2005-0152849 on July 14, 2005, listed as reference AB on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 10/257,886, "Pharmaceutical Formulations for Dry Powder Inhalers," filed June 6, 2003; published as U.S. Publication No. 2003-0185764 on October 2, 2003, listed as reference AC on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 10/257,790, "Formulations for Use in Inhaler Devices," filed May 5, 2003; published as U.S. Publication No. 2003-0175214 on September 18, 2003, listed as reference AD on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 10/257,883, "Formulations for Use in Inhaler Devices," filed March 26, 2003; published as U.S. Publication No. 2003-0165436 on September 4, 2003, listed as reference AE on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 10/312,488, "Method of Making Particles for Use in a Pharmaceutical Composition," filed March 11, 2003; published as U.S. Publication No. 2003-0162835 on August 28, 2003, listed as reference AF on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 10/433,072, "Method of Making Particles for Use in a Pharmaceutical Composition," filed September 12, 2003; published as U.S. Publication No. 2004-0037785 on February 26, 2004, listed as reference AG on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 10/433,185, "Pharmaceutical Compositions for Inhalation," filed September 12, 2003; published as U.S. Publication No. 2004-0047810 on March 11, 2004, listed as reference AH on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 10/433,135, "Particles for Use in a Pharmaceutical Composition," filed November 28, 2003; published as U.S. Publication No. 2004-0071635 on April 15, 2004, listed as reference AI on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 10/571,146, "Dry Powder Composition Comprising Co-jet Milled Particles for Pulmonary Inhalation," filed March 9, 2006;

U.S. Patent Application Serial No. 10/552,326, "Devices and Pharmaceutical Compositions for Enhancing Dosing Efficiency," filed March 20, 2006; and

U.S. Patent Application Serial No. 10/571,884, "Dry Powder Composition Comprising a Benzodiazepine for Pulmonary Inhalation," filed March 13, 2006.

Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii), the Examiner's attention is directed to Appendix A, attached hereto, which contains the following:

- 1) Specification and pending claims of U.S. Patent Application Serial No. 10/571,146;
- 2) Specification and pending claims of U.S. Patent Application Serial No. 10/552,326;  
and
- 3) Specification and pending claims of U.S. Patent Application Serial No. 10/571,884.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 (1 sheet) be considered and made of record.

The present Information Disclosure Statement is filed under 37 C.F.R. §1.97(b), before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due. However, if it is determined that any fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

Respectfully submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

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FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.: 478.1074

SERIAL NO.: 10/570,902

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): David MORTON et al.

FILING DATE: March 9, 2006

GROUP:

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6	4	7	5	5	2	3	11/05/02	Staniforth	424	070.100	
	AB	20	05	01	52	8	4	9	07/14/05	Staniforth	424	489	
	AC	20	03	01	85	7	6	4	10/02/03	Staniforth et al.	424	045	
	AD	20	03	01	75	2	1	4	09/18/03	Staniforth et al.	424	045	
	AE	20	03	01	65	4	3	6	09/04/03	Staniforth et al.	424	045	
	AF	20	03	01	62	8	3	5	08/28/03	Staniforth et al.	424	046	
	AG	20	04	00	37	7	8	5	02/26/04	Staniforth et al.	424	046	
	AH	20	04	00	71	6	3	5	04/15/04	Staniforth et al.	424	046	
	AI	20	04	00	47	8	1	0	03/11/04	Staniforth et al.	424	046	
	AJ												
	AK												
	AL												
	AM												
	AN												
	AO												
	AP												

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AQ													

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.